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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,516	09/08/2003	Francois Binette	022956-0225	7793

21125 7590 01/08/2007

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EXAMINER	
QIAN, CELINE X	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/657,516	BINETTE ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-47* is/are pending in the application.

4a) Of the above claim(s) *25-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 and 6-47 are pending in the application. Claims 25-47 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-4 and 6-24 are currently under examination.

This office action is in response to the Amendment filed on 10/30/06.

Response to Amendment

The objection to claim 5 is moot in light of Applicant's cancellation of the claim.

The rejection of claims 1-4 and 6-24 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of Applicant's amendment.

The rejection claims 1-3, 5-15 and 17-24 under 35 U.S.C. 102 is maintained for reasons set forth of the record mailed on 7/17/06 and further discussed below.

The rejection of claims 4 and 16 under 35 U.S.C. 103 (a) is maintained for reasons set forth of the record mailed on 7/17/06 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-14 and 17-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Glorioso et al (US 6,413,511, IDS).

Claims 1-3 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartholomew et al (Human Gene Therapy, 2001, Vol.12, pages 1527-1541, IDS).

In response to this rejection, Applicants argue that the reference does not teach the use of genetically altered chondrocytes expressing a therapeutic agent to treat disorders in an environment atypical for chondrocytes. Applicants argue claim 1 requires the chondrocyte to function only as delivery vehicle for expressing and delivering the therapeutic agent required for alleviating the disease condition without becoming an integral part of the tissue or organ where the chondrocytes are delivered. Applicants also argue that Bartholomew et al. does not teach the use of genetically modified chondrocytes to deliver therapeutics for in vivo repair of a diseased tissue, or delivering the chondrocytes to a diseased environment atypical to chondrocytes. Furthermore, Applicants assert that Bartholomew does not disclose the direct use of genetically modified chondrocytes to repair tissue damage in a region not associated with chondrocytes. Applicants thus conclude that the claimed invention is not anticipated by both references.

The above argument has been fully considered but deemed unpersuasive. As discussed in the previous office action, since the instant claims are drawn to a product, a genetically altered chondrocyte (not a method of delivering said chondrocyte), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the intended use of the chrondrocyte does not impart a structural difference with what's

disclosed in the prior art. The instant specification discloses in the working example of isolating primary chondrocytes from human and bovine, culturing said chondrocytes *in vitro*, and transfecting said chondrocytes with constructs encoding GFP or EPO to said chondrocytes *in vitro*. The instant specification does not teach or give an example of a genetically modified chondrocyte which serves as a delivery vehicle for delivering a therapeutic agent to a diseased tissue in an atypical chrondrocyte environment and treating said disease, wherein said chondrocyte does not become part of the structural component of the environment. As such, one cannot envision the structural difference of the claimed genetically modified chondrocyte from the genetically modified chondrocyte disclosed in Glorioso or Bartholomew in order for them to have the function as a delivery vehicle only but not become a structural component of the environment. Since the claim encompasses both *in vitro* and *in vivo* setting, the teaching of Bartholomew anticipates the claims because the genetically modified MSC can differentiate into chondrocytes *in vivo*, thus become a genetically altered chondrocyte. The instant claims are not drawn to method of delivering the genetically modified chondrocytes, thus a direct delivery of the chondrocyte is not a limitation of the claims. Therefore, for reasons discussed in previous office action and above, this rejection is maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomew et al.

In response to this rejection, Applicants argue Bartholomew does not teach the use of genetically modified chondrocytes for *in vivo* delivery hEPO mimetibody as a therapeutic agent. Applicants further argue that the *in vivo* expression of functional mimetibodies is not a trivial task, which it would require the designing of a vector to express the protein of interest in a form that would allow it to assert its desired therapeutic effect. Applicants argue that Bartholomew does not disclose the sequence encoding an EPO mimetibody, thus one of ordinary skill in the art would not know how to design such vector in altered chondrocytes and build Applicant's invention. Applicants thus conclude that the invention is not obvious in view of the teaching of Bartholomew et al.

The above arguments have been fully considered but deemed unpersuasive. Applicants are reminded that the claims 4 and 16 are drawn to a genetically altered chondrocyte that may be used for expressing an EPO mimetibody, not a method of delivering therapeutic EPO mimetibody using a genetically modified chondrocytes. As such, the reference does not have to disclose features such as the step of delivering the genetically altered chondrocyte because it is intended use, not a limitation of the claim. Further, the claim does not require the EPO mimetibody to have any therapeutic function because that is not part of the claim limitation either. At the time of filing, the gene encoding epo has already been well characterized and its function ascribed to regions that bind to the corresponding receptor. It would have been obvious to one of ordinary skilled in the art to make a construct that expresses an erythropoietin mimetibody. Such application would have been routine experimentation to an ordinary artisan. Applicants are again reminded although Applicant's invention may be a method of using a genetically altered chondrocyte to deliver therapeutic agent to an atypical site of the chondrocyte,

what is claimed is a genetically altered chondrocyte, of which the intended use does not impart a structural difference from what is disclosed in the prior art based on the disclosure of the specification. Therefore, for reasons discussed in previous office action and above, this rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER